

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

ROBERT STRINI and TERRY STRINI,

Plaintiffs,

-against-

EDWARDS LIFESCIENCES CORPORATION, EDWARDS
LIFESCIENCES LLC, EDWARDS LIFESCIENCES (U.S.),
INC., and EDWARDS LIFESCIENCES
CARDIOVASCULAR RESOURCES, INC.

Defendants.

COMPLAINT

**TRIAL BY JURY IS
DEMANDED**

Plaintiffs, Robert Strini and Terry Strini, by and through their attorneys, DeGraff, Foy, Kunz & Devine, LLP, complaining of the defendants, allege upon information and belief as follows:

SUMMARY OF CLAIM

1. This action seeks, *inter alia*, damages for personal injury, pain, suffering, economic loss, the cost of past and future medical care, and loss of consortium sustained by plaintiffs Robert Strini and Terry Strini, due to the liability of the defendants, based on negligence, strict products liability, and breach of warranty arising from the defendants' manufacture, distribution and sale of a contaminated bioprosthetic heart valve surgically placed in Robert Strini.

JURISDICTION

2. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. § 1332 in that the amount in controversy exceeds the sum of Seventy Five Thousand and 00/100 (\$75,000.00) Dollars exclusive of interest and costs, and this action is between the plaintiffs, citizens of the State of New York, and the defendants, citizens of the State of California, Delaware,

Pennsylvania, or in the alternative, citizens of a state other than the State of New York.

3. This Court further has supplemental jurisdiction of this action pursuant to 28 U.S.C. § 1367(a).

PARTIES

4. The plaintiff, Robert Strini, is an individual residing in Rhinebeck, New York.

5. The plaintiff, Terry Strini, is an individual residing at 315 Overlook Drive, Hurley, New York.

6. At all times relevant to this action, Robert Strini and Terry Strini were husband and wife.

7. The defendant, Edwards Lifesciences Corporation, (“ELC”) is a foreign corporation organized and existing pursuant to the laws of the State of California or some state other than the State of New York.

8. Defendant ELC is authorized to do business in the State of New York.

9. The defendant, Edwards Lifesciences LLC, (“LLC”) is a foreign corporation organized and existing pursuant to the laws of the State of Delaware or some state other than the State of New York.

10. LLC is authorized to do business in the State of New York.

11. Edwards Lifesciences (U.S.), Inc. (“ELUS”) is a foreign corporation organized and existing pursuant to the laws of the State of Delaware, or some state other than the State of New York.

12. ELUS is authorized to do business in the State of New York.

13. Edwards Lifesciences Cardiovascular Resources, Inc. (“ELCRI”) is a foreign

corporation organized and existing pursuant to the laws of the State of Pennsylvania, or some state other than the State of New York.

14. ELCRI is authorized to do business in the State of New York.

15. At all times relevant hereto, defendants ELC, LLC, ELUS, and/or ELCRI (“Defendants”) were engaged in the business of designing, developing, manufacturing, testing, inspecting, advertising, selling, transporting, marketing, promoting, and distributing bioprosthetic heart valves including but not limited to the 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800, surgically implanted in the plaintiff Robert Strini on or about April 9, 2002.

16. Prior to April 9, 2002 defendants did, in the normal course of business, sell, transfer, deliver, or otherwise place in the stream of commerce the aforesaid 27mm bovine bioprosthesis, and conducted business in and had and continue to have significant purposeful, and deliberate business contacts with and in the State of New York.

FIRST CLAIM FOR RELIEF
(Negligence)

17. Plaintiffs repeat and reallege each and every allegation set forth in paragraphs “1” through “16” above as if fully set forth herein at length.

18. On or about April 9, 2002 plaintiff Robert Strini underwent cardiac surgery for replacement of an aortic valve at St. Peters Hospital, Albany, New York.

19. During the aforesaid surgery a 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800, manufactured and distributed by defendants was used to replace plaintiff Robert Strini’s defective aortic valve.

20. At the time of the aforesaid surgery the 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800, was contaminated with mycobacterium and not in a sterile condition suitable for surgical placement in the plaintiff Robert Strini.

21. On or about August 9, 2002 the plaintiff Robert Strini was required to undergo another aortic valve replacement surgery to remove the contaminated bovine bioprosthetic heart valve at St. Peters Hospital.

22. As a result of the contaminated 27mm bovine bioprosthesis, serial number HT3773, Model 2800, the plaintiff Robert Strini suffered infection, associated complications, stroke, and the need for additional surgery, causing him serious, painful, disabling, and permanent personal injuries.

23. The aforesaid infection, complications, stroke, surgery, and serious, painful, disabling and permanent personal injuries sustained by the plaintiff Robert Strini were directly and proximately caused by and due to the negligence of the defendants, without any negligence on the part of the plaintiff Robert Strini contributing thereto.

24. The negligence of the defendants consisted, among other things, of the following:

- (a) in designing, manufacturing, and/or distributing for sale said 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800, in a dangerous and defective condition, which exposed the plaintiff Robert Strini to an unreasonable risk of harm, with the result that he suffered serious, painful, disabling and permanent personal injuries;
- (b) in designing, manufacturing, and/or distributing for sale said 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800, which was in a

dangerous and defective condition due to the fact that it was contaminated with mycobacterium which exposed the plaintiff Robert Strini to an unreasonable risk of harm, with the result that he suffered serious, painful, disabling, and permanent personal injury;

(c) in failing to appropriately and completely sterilize the said 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800;

(d) in failing to conduct proper adequate testing to ascertain whether the said 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800 was appropriately sterilized and free from dangerous contaminants;

(e) in designing, manufacturing, and/or distributing for sale the said 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800 which did not satisfy or conform to applicable Federal and State statutes, rules, and regulations;

(f) in promoting the use of said 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800;

(g) in failing to use materials fit, adequate, safe, or appropriate in the manufacture of said 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800;

(h) in causing and permitting said 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800 to be unfit for normal use as a medical replacement for a damaged human aortic valve, in that it failed to meet proper safety and quality standards, thereby exposing the plaintiff Robert Strini to risk of harm;

(i) in failing to properly, adequately, and appropriately inspect the said 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800 and discern it

was in a defective and dangerous condition;

(j) in failing to take ordinary safeguards and prudent precautions to prevent the contamination of said 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800 and the occurrence of injury to the plaintiff Robert Strini;

(k) in failing to properly, adequately, and appropriately warn of the risks and damages associated with the use of the said 27mm bovine bioprosthetic heart valve;

(l) in being otherwise careless and negligent.

25. As a result of the aforesaid negligence of the defendants, the plaintiff Robert Strini suffered serious physical injuries, pain and suffering, and was rendered and continues to be sick, sore, lame, and disabled, which injuries and disability will be permanent.

26. Plaintiff Robert Strini has incurred and will incur in the future considerable expense for his medical care, hospital care, nursing home care, and treatment.

27. By reason of the foregoing, the plaintiff, Robert Strini was damaged in an amount to be determined by the Court but not less than Ten Million and 00/100 (\$10,000,000.00) Dollars, together with interest thereon as permitted by law.

SECOND CLAIM FOR RELIEF
(Strict Products Liability)

28. Plaintiffs repeat and reallege each and every allegation set forth in paragraphs “1” through “27” above as though fully set forth herein at length.

29. Upon sale of the aforesaid 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800, the defendants assumed a strict liability to all persons whom they could

reasonably foresee would be injured by the sale of a bioprosthetic heart valve that was contaminated and not safe for its intended medical use.

30. The plaintiff Robert Strini was covered by and included in the aforesaid assumption of strict liability.

31. On April 9, 2002 the aforesaid 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800 was a defective product within the meaning of the doctrine of strict products liability because it could not be used safely as a result of the dangerous, hazardous, and defective manufacture, design and condition as set forth herein.

32. The aforesaid 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800 was defective when it left defendants' facilities, and at the time of its sale, and remained defective up until the time of its surgical placement into the plaintiff Robert Strini on or about April 9, 2002 and thereafter.

33. As a direct and proximate result of the defective condition of the 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800, the plaintiff Robert Strini sustained serious physical injuries, pain and suffering and permanent disability.

34. By reason of the foregoing the plaintiff, Robert Strini was damaged in an amount to be determined by the Court but not less than Ten Million and 00/100 (\$10,000,000.00) Dollars, together with interest thereon as permitted by law.

THIRD CLAIM FOR RELIEF
(Breach of Express and Implied Warranty)

35. Plaintiffs repeat and reallege each and every allegation set forth in paragraphs "1" through "34" above as though fully set forth herein at length.

36. Upon the manufacture and sale of the aforesaid 27mm bovine bioprosthetic heart valve serial number HT3773, Model 2800, and prior to the transfer and sale thereof, and prior to its use and surgical implantation in plaintiff Robert Strini on or about April 9, 2002, defendants made certain express and implied warranties to the consuming public including the plaintiff Robert Strini concerning the 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800.

37. Upon the manufacture and sale of the aforesaid 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800, and prior to the transfer and use thereof, defendants expressly and impliedly warranted to the consuming public and the plaintiff Robert Strini that the aforesaid 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800 was of merchantable quality and reasonably fit, safe and suitable for its intended purpose.

38. The said 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800 was not of merchantable quality, nor fit, safe, nor suitable for its intended purpose.

39. The aforesaid 27mm bovine bioprosthetic heart valve, serial number HT3773, Model 2800 did not conform to the express and implied warranties rendered by the defendant ELC.

40. The plaintiff Robert Strini was not aware of, and could not have discovered the defect of the aforesaid 27mm bovine bioprosthetic heart value, serial number HT3773, Model 2800 which made the product unreasonably dangerous, unsafe, unfit, and unsuitable for its intended use and not of merchantable quality.

41. The severe, painful, and permanent injuries and disability suffered by plaintiff Robert Strini were brought about as a direct and proximate result of the breach of the express and implied warranties by the defendants.

42. By reason of the foregoing, the plaintiff Robert Strini has been damaged in an amount to be determined by the Court but not less than Ten Million and 00/100 (\$10,000,000.00) Dollars, together with interest thereon as permitted by law.

FOURTH CCLAIM FOR RELIEF
(Consortium)

43. Plaintiffs repeat and reallege each and every allegation set forth in paragraphs “1” through “42” above as though fully set forth herein at length.

44. At all times mentioned, plaintiffs Robert Strini and Terry Strini were and remain husband and wife, and plaintiff Terry Strini enjoyed the society, comfort, services, and companionship of her husband prior to the injuries and disability caused by the defendants as described herein.

45. As a result of the injuries and permanent disability of the plaintiff Robert Strini, the plaintiff Terry Strini was and will be deprived of his society, comfort, services, and companionship all to her damage.

46. By reason of the foregoing, the plaintiff Terry Strini has been damaged in an amount to be determined by the Court but not less than Two Million and 00/100 (\$2,000,000.00) Dollars, together with interest thereon as permitted by law.

WHEREFORE, plaintiffs Robert Strini and Terry Strini demand judgment in their favor and against the defendants on each claim for relief together with interest thereon as permitted by

law, costs and disbursements of this action, and such other and further relief as the Court deems just and proper.

DATED: Albany, New York
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DAVID F. KUNZ, ESQ.
Bar Roll No. 103198
DEGRAFF, FOY, KUNZ & DEVINE, LLP
Attorneys for Plaintiffs
90 State Street
Albany, NY 12207
(518) 462-5300